

**REMARKS**

Claims 1-73 are pending in this application. Claim 11 is cancelled.

**The Amendments**

The amendments in Claims 1, 13-16, 26, 27, 28, 36, 41, 42, 46 and 57 are supported, for example, by cancelled claim 11; page 4, lines 6-7; page 13, lines 21-23; page 20, line 4 to page 26, line 21; page 33, lines 13-18; page 35, lines 3-10; page 42, lines 4-9.

No new matter is added in the amendments. The Examiner is respectfully requested to enter the amendments.

**The Response**

**Objections to the Oath/Declaration**

The Oath/Declaration is objected to by the Examiner because the joint inventors allegedly executed separate oaths without making reference to the fact to each of the other joint inventors. In addition, the provisional application number was misprinted on the declaration.

Applicants enclosed herewith a new executed Oath/Declaration that explicitly makes reference to the fact that the affiant is a joint inventor together with each of the other inventors. Applicants have also corrected the misprinted provisional application number on the declaration. However, Applicants respectfully point to language in the former oath/declaration, executed on April 1, 2002 with respect to Mr. Drinan and Dr. Edman, and on April 9, 2002 with respect to Dr. Merz, that specifically references there are joint inventors in regards to the executed combined Oath/Declaration and Power of Attorney. In particular, Applicants state on page 1 "or an original, first and joint inventor (if plural names are listed below)." Since there are a plurality of names listed on the Oath/Declaration, Applicants have therefore explicitly made reference to the fact that the affiant is a joint inventor together with each of the other named inventors.

In light of these remarks and the attached executed Oath/Declaration, the objection should be withdrawn.

**35 U.S.C. § 112 Second Paragraph Rejection**

Claims 13-16, 20, 21, 24-28, 57-64 and 69 are rejected under 35 U.S.C. § 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim

the subject matter to which Applicant regards as his invention. This rejection is traversed in part and overcome in part in view of the amendments.

Claims 26, 27, 57 and 69 have been amended to correct the insufficient antecedent basis for this limitation in the claim. The 35 U.S.C. § 112 rejection should be withdrawn in light of the amendments.

In regards to Claims 13-16, 20, 21, 24 and 28 the Examiner alleges that it is unclear how the recited structural features further limit the method claim. The recited structural features limit method Claims 13-16 and 28 by further defining the term “attached” and “communicating” in reference to its placement on the mammalian subject, as recited in Claim 1. Claims 13, 14 and 28 have been amended to explicitly refer to the “attached” limitation in Claim 1. Claims 15 and 16 have been amended to explicitly refer to the “communicating” recitation in Claim 1.

In regards to Claims 20, 21 and 24, the recited structural features of the data collection unit being “attached to the mammalian subject” (Claim 20), “remotely located relative to the mammalian subject” (Claim 21) or “configured to allow data processing and storage for future transmission” (Claim 24) make clear that the individual dependent method claims are further limiting the method of Claim 1 by defining the location of the data collection unit relative to the mammalian subject. The specification provides ample support for the flexibility of the data collection unit localization relative to the mammalian subject, and takes into account the many uses of the system where the necessity for storage of received information when a database management system is not available for downloading of information. *See* page 4, lines 6-7; page 13, lines 21-23; page 33, lines 13-18; page 42, lines 4-9. Depending upon the needs of the system, the data collection unit may be attached via a hardwire connection to the mammalian subject, or may be remotely located relative to the mammalian subject, and in communication with the system via a wireless link. Therefore, Applicants believe that the recited structural features further limit the method claim, and has ample support in the instant specification.

The 35 U.S.C. § 112 rejection should be withdrawn in light of these amendments and remarks.

### **35 USC §102(e) Rejection (Jacobsen)**

Claims 1-17, 20-27, 29-40, 42-54, 56, 65 and 67-71 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Jacobsen, et al. (U.S. Patent No. 6,198,394). The rejection to

the claims is respectfully traversed in part and overcome in part in view of the amendments above.

The Examiner alleges that the term “summarized” is not defined in the specification. Applicants respectfully disagree with the Examiner, and submit that the specification, as well as the knowledge of one of ordinary skill in the art, would conclude that summarized data is not data in a format other than binary code. Rather, summarized data is data that has been analyzed and presented to the mammalian subject or other authorized personnel as a summary, i.e. as covering the main points succinctly. *See Merriam-Webster Dictionary definitions of “summarize” and “summary”, attached herein.*

Thus, the specification provides that as part of the database management system, “(c)ustom algorithms and neural analysis will be used to interpret the collected data, with measured subject or clinician controlled customizable variables. This analysis will be **summarized.**” Page 33, lines 20-22 (emphasis added). In addition, the examples provided in the specification illustrate what type of summaries are presented to the mammalian subject or other authorized personnel. In regards to the detection of an infected individual in a herd, the device analyzes the data presented, and submits to a farmer summarized data indicating the identification of the afflicted individual. Page 39, lines 19-33. Therefore, Applicants have provided ample definition within the specification, as well as what is known by one of ordinary skill in the art, to define the term “summarized” as providing the further analysis of data in a summary fashion, and not merely in a format other than binary code. Applicants wish to additionally point out that the summarized data in the instant application refers to physiological data only. The instant application does not provide a means for geographically locating a mammalian subject and determining his position.

In contrast, Jacobsen does not provide a means for presenting summarized data to the mammalian subject or other authorized medical personnel, and is greatly concerned with the geographical location of its soldier subject. Jacobsen discloses a wearable apparatus with a sensor means, wherein a means for transmitting data to a remote location is localized to one of a pocket means in the wearable apparatus. *See Claim 1.* The wearable apparatus is comparatively large (approximately 5 pounds), and is meant to be worn as a harness with a soldiers equipment. *See col. 6, lines 58-63.*

The Jacobsen invention is designed for use on the battlefield or during training exercises. Col. 1, lines 6-9. As such, Jacobsen provides for a device amenable to warfare situations, including the preferred use of short bursts (col. 7, lines 39-42) to avoid tracking by an enemy. Jacobsen also provides a means for locating soldiers through a GPS mechanism, in order to avoid friendly fire situations, and to monitor potential fratricide situations. *See* Claim 1; col. 3, lines 4-7. Jacobsen provides a means to transmit remote location information, unlike the instant application. The instant application does not contemplate the use of a GPS system, nor does it contemplate the need to locate an individual as part of its system.

Jacobsen provides for a means to transmit data indicating multiple physiological parameters. Jacobsen does not provide a means for summarizing data, but instead merely presents data that has been transmitted from the soldier unit to a medic/leader unit or command unit. Col. 4, line 40 et seq. Such information includes body temperature, heart rate, body positions, blood pressure, temperature, heart rate, etc. Col. 4, lines 14-18. Therefore, the system provides means to monitor a soldier's physiological status in detail, but does not present to the mammalian subject or other authorized personnel already analyzed and summarized data.

Moreover, Jacobsen does not provide for encryption of data, a shortcoming that greatly increases the potential for cross-talk between subjects, but also increases a likelihood for a privacy invasion concern. The instant application provides for the encryption of data, and as such Applicants have amended the claims to recite the requirement for the encryption of data sent by the subject.

In light of these remarks, the 35 U.S.C. § 102(e) rejection in view of Jacobsen should be withdrawn.

### **35 USC §102(e) Rejection (Flach)**

Claims 1-3, 6, 7, 10-13, 15, 18, 19, 21-24, 28-30, 33-36, 41-44, 50, 51, 56, 65 and 66 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Flach et al. (U.S. Patent No. 6,213,942). The rejection to the claims is respectfully traversed.

Flach et al. disclose a means for transmission of signals between and a patient telemetry unit and multiple ceiling-mounted transceiver units (VCELLSs) that are fixed throughout a building facility, for example a hospital. *See* col. 3, lines 28-54. To protect against multipath interference or other cause of data loss, each remote telemeter must maintain contact with two

VCELLs at a time. Col. 4, lines 13-16. This results in redundant transmission of patient data to a remote collector over two separate data paths. *See* Col. 4, lines 24-26, Claim 1. The instant application does not require the loosely equivalent data collection unit (DCU) to be ceiling mounted and fixed to a location throughout a building facility. The instant application also does not require redundant transmission of patient data to a remote collector over two separate data paths. Instead, the instant application contemplates the use of a DCU as being more flexible in the operation of the system. For example, DCU's in the instant application can relay information between other DCU's until a remote database management unit is located. *See* Claim 41. This improves the performance of the system, and overcomes problems inherent in RF transmission systems, as is present in the Flach invention. In addition, redundant transmission of data packets claimed and disclosed by Flach is not contemplated by the instant application. The instant application is distinct from Flach, and therefore is not anticipated.

The Flach patent also contemplates the use of a hardwire design on the VCELLs for communicating with a central collector, while communicating with a remote telemeter using a wireless TDMA protocol (RF transmission of data). This hardwire design between a VCELL and the central collector removes the possibility of VCELL to VCELL communication. In contrast, the instant application contemplates the use of DCU to DCU communication as a means of locating a remote database management unit when the subject is out of range. *See* Claim 41. The Flach invention cannot reach outside parameters of the building, and is thus limited by the hardwire constraints disclosed. The instant application is distinct from Flach, and therefore is not anticipated.

Moreover, Flach does not contemplate the use of communication with the user from a database management system, as the instant application claims. Instead, Flach merely interrogates the remote telemetry device regarding availability of a specific VCELL for data packet unloading and transmission, as well as monitoring the quality of the RF link from each remote telemeter to a specific VCELL. Col. 8, lines 9 et seq. Thus, Flach does not contemplate the use of "providing feedback of said summarized data to said mammalian subject or other authorized personnel through a communication means" as required in Claims 1, 36, 41 and 42, and related dependent claims after the data is collected by the database management unit. Instead, Flach requires a user to monitor the database management unit for any changes in a patients condition or location. *See* Col. 7, lines 44-57.

In light of these remarks, the 35 U.S.C. § 102(e) rejection in view of Flach should be withdrawn.

### 35 USC §103(a) Rejection

Claims 14, 55 and 57-64 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Jacobsen et al. or Flach et al. as applied to Claims 1 and 50, and further in view of Gowda et al. (U.S. Patent Application No. 6,459,917). This rejection is traversed in part and overcome in part in view of the amendments.

Gowda et al. discloses a structure having a lower chamber for sample collection and an upper chamber connected to the dermal support, which is separated by a septum. The septum, an integral part of the device, is subsequently manually pierced by a needle, capillary tube or other aspirating device by a practitioner for access to body fluids. *See* col. 4, lines 1-4; col. 4, lines 7-10. Therefore, a practitioner must first manually pierce the septum by some sharp means in order to sample body fluids in order to practice the Gowda invention. As a result of its structure, the septum also physically forms separate chambers, the lower chamber containing filtered bodily fluids, and the upper chamber which contacts the outside surface. *See* Figures 1B, 1E, 2A, 2B, 2C et seq. The septum acts as a physical barrier between the upper and lower chambers.

Because of the need to physically pierce the septum to access body fluids for sampling, Gowda specifically calls for a conduit of stainless steel tubing or other rigid biocompatible material. Col. 5, lines 61-64. Alternatively, the conduit may be formed integrally with the rigid housing.

In contrast, the instant application calls for the use of a flexible transdermal conduit, <sup>not claimed</sup> which guides a sensor assembly comprising the BIH. The sensor assembly interfaces with the biofluid access port located on a second end of the transdermal conduit. Therefore, one of ordinary skill in the art would not have looked to the Gowda reference in view of Flach et al. or Jacobsen et al. because it does not meet the needs of the instant application inasmuch as a flexible conduit is required to practice the instant application. A flexible conduit, as recited in the instant specification are “elements for comfort and acceptance of this implant technology.” *See* page 21, lines 11-24.

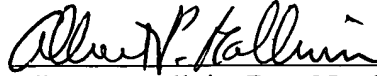
Applicants in their amendments emphasize the differences between the instant application and the combination of Gowda in view of Flach or Jacobsen. Applicants have amended Claim 57 to more particularly point out features of the instant application by adding a limitation for a flexible transdermal conduit, and pointing out the limitation of the presence of microstructures capable of allowing analytes to flow into the transdermal conduit to contact the sensor assembly and block transmission of external pathogens into a subject. In light of the remarks and the amendments, the 35 U.S.C. § 103(a) rejection should be withdrawn.

**CONCLUSION**

Applicants believe that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109.

Respectfully submitted,

Date: September 8, 2003



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One entry found for **summarize**.

Main Entry: **sum·ma·rize**

Pronunciation: 's&-m&-'rIz

Function: *verb*

Inflected Form(s): -rized; -riz·ing

Date: 1871

*transitive senses* : to tell in or reduce to a summary

*intransitive senses* : to make a summary

- **sum·ma·riz·able** /'s&-m&-'rI-z&-b&l/ *adjective*

- **sum·ma·riz·er** *noun*

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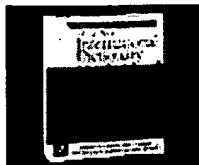
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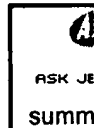
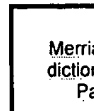
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dictionaryMain Entry: **1**sum·ma·ry

Pronunciation: 's&amp;-m&amp;-rE also 's&amp;m-rE or -"mer-E

Function: *adjective*Etymology: Middle English, from Medieval Latin *summarius*,  
from Latin *summa* sum

Date: 15th century

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succinctly**2 a** : done without delay or formality : quickly executed <a  
*summary* dismissal> **b** : of, relating to, or using a summary  
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